By Royal Charter

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** **CE 01966**

Issued To: **Mölnlycke Health Care AB**
**Box 13080**
**Gamlestadsvägen 3C**
**SE-402 52 Göteborg**
**Sweden**

In respect of:

**See certificate scope page.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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Certificate No: CE 01966

# Certificate Scope:

**Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.**

**Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.**

**Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.**

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number: **MD 83345**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21
Effective Date: 2018-11-28
Latest Revision Date: 2018-11-26
Expiry Date: 2021-11-27



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Certificate No: **MD 83345**

| Location | Registered Activities |
|---|---|
| Mölnlycke Health Care AB<br>Box 13080<br>Gamlestadsvägen 3C<br>SE-402 52 Göteborg<br>Sweden | The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.<br>The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments. |
| Molnlycke Health Care Pty Ltd<br>Level 4<br>12 Narabang Way<br>Belrose<br>New South Wales<br>2085<br>Australia | The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments. |

Original Registration Date: 2004-07-21

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

*This is to certify that:*

**Mölnlycke Health Care AB**
**Gamlestadvägen 3 C**
**S-402 52**
**Göteborg**
**Sweden**

*Holds Certificate No:* **FM 39247**

*and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:*

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

*For and on behalf of BSI:*

*Managing Director, BSI Management Systems (CEMEA)*

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

UKAS QUALITY MANAGEMENT 003

*Certificate No:* **FM 39247**

| ***Location*** | ***Registered Activities*** |
|---|---|
| Mölnlycke Health Care AB<br>Gamlestadsvägen 3 C<br>S-402 52 Göteborg<br>Sweden | The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.<br><br>The design, development and manufacture of pharmaceuticals and other healthcare products. |
| Mölnlycke Health Care Oy<br>PO Box 76<br>Saimaankatu 6<br>Mikkeli<br>FIN 50101<br>Finland | Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs. |
| Mölnlycke Health Care AB<br>Mölnlycke Health Care (Thailand) Lt<br>160 Bangplee Industrial Estate<br>Bangna-Trad Rd<br>Samutprakarn<br>Bansaothong<br>10540<br>Thailand | Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing. |
| Mölnlycke Health Care AB<br>T/A Mölnlycke Health Care SA<br>Parc Industrial<br>B-4300 Waremme<br>Belgium | Manufacture of sterile drapes, operating sets and procedure packs. |
| Mölnlycke Health Care Klinipro s.r.<br>Na Novem Poli 382<br>Prumyslova zona Karvina<br>Karvina - State Mesto<br>733 01<br>Czech Republic | Manufacture of surgical drapes and procedure packs. |

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

*Certificate No:* **FM 39247**

| ***Location*** | ***Registered Activities*** |
|---|---|
| Mölnlycke Health Care AB<br>Mölnlycke Health Care (Thailand) Lt<br>Amata Nakorn (Bang Pakong)<br>Industrial Estate<br>700/461 Moo Bangha-Trad Rd. KM.57<br>Tambol Donhuaroh, Amphur Muang<br>Chonburi 20000<br>Thailand | Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing. |
| Mölnlycke Health Care AB<br>Tubiton House<br>Medlock Street<br>Oldham<br>OL1 3HS<br>United Kingdom | The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products. |
| Mölnlycke Health Care AB<br>Lot 9, Lorong Perusahaan 4<br>Kulim Industrial Estate<br>PO Box 52, 09000 Kulim<br>Kedah Darulaman<br>Malaysia | The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves. |
| Mölnlycke Health Care AB<br>Plot 204 Kawasan Perindustrian<br>Kula Ketil<br>Phas II<br>09300 Kula Ketil<br>Malaysia | The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves. |
| Mölnlycke Health Care AB<br>Lot B5 & B6<br>Kawasan Perindustrian Miel<br>Batang Kali Phase II<br>44300 Batang Kali<br>Malaysia | The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves. |

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

| | |
|---|---|
| Trade name/ Product name: | **Surgical and Equipment Drapes (Sets)** |

| | |
|---|---|
| Product classification: | **IS** |
| Sterility Status: | **Sterile** |
| Measuring function: | **No** |

| | |
|---|---|
| This declaration is supported by a conformity assessment procedure in accordance with | |
| Annex/es: | **V, VII** |

| | |
|---|---|
| Certificate number: | **CE 01966** |
| Issued by: | **BSI (0086)** |
| For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body. | |

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2018-11-16** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** Signature:

## Product(s) covered by this declaration:

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 1218 | E.N.T. SET | 33961 |
| 251 | LITHOTOMY SET | 33961 |
| 282 | SET-UP SET | 33961 |
| 306480 | DENTAL SET | 33961 |
| 565710 | GYNAECOLOGY SET | 33961 |
| 60001 | SHOULDER SET | 33961 |
| 60002 | SHOULDER SET W/POUCH | 33961 |
| 60003 | BEACH CHAIR SHOULDER SET | 33961 |
| 60005 | SHOULDER SPLIT SHEETS W/POUCH | 47783 |
| 60101 | KNEE ARTHROSCOPY SET | 33961 |
| 60102 | KNEE ARTHROSCOPY SET | 33961 |
| 60103 | KNEE ARTHROSCOPY SET | 33961 |
| 60200 | EXTREMITY SET | 33961 |
| 60202 | EXTREMITY SET | 33961 |
| 60203 | EXTREMITY SET | 33961 |
| 60204 | EXTREMITY SET | 33961 |
| 60205 | EXTREMITY SET | 33961 |
| 60206 | EXTREMITY SET | 33961 |
| 60207 | EXTREMITY SET | 33961 |
| 60208 | EXTREMITY SET | 33961 |
| 60209 | EXTREMITY SET | 33961 |
| 60300 | EXTREMITY SET, BILATERAL FOOT | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 60301 | EXTREMITY SET, BILATERAL LEG | 33961 |
| 60302 | HAND AND FOOT SET | 33961 |
| 60303 | HAND AND FOOT SET | 33961 |
| 60305 | HAND SET | 33961 |
| 60306 | HAND SET | 33961 |
| 60307 | HAND SET | 33961 |
| 60602 | HIP SET W/DISLOCATION BAGS | 33961 |
| 60603 | HIP SET | 33961 |
| 60604 | HIP SET | 33961 |
| 60606 | HIP SET | 33961 |
| 60607 | HIP SET | 33961 |
| 60608 | HIP SET | 33961 |
| 60609 | HIP SET | 33961 |
| 60610 | HIP SET | 33961 |
| 60611 | HIP SET | 33961 |
| 60612 | HIP SET | 33961 |
| 60613 | HIP SET | 33961 |
| 60614 | HIP SET | 33961 |
| 60615 | HIP SET | 33961 |
| 60616 | HIP SET | 33961 |
| 60617 | SPLIT SHEET SET | 33961 |
| 60618 | SPLIT SHEET SET | 33961 |
| 60619 | ORTHOPAEDIC SET | 33961 |
| 60620 | SPLIT SHEET SET | 33961 |
| 61010 | LITHOTOMY SET | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 61020 | LITHOTOMY SET | 33961 |
| 61030 | LITHOTOMY SET | 33961 |
| 61040 | LAPAROSCOPY SET | 33961 |
| 61400 | VARICOSE VEIN SET | 33961 |
| 61450 | Laparoscpy Set Bariatric | 33961 |
| 61800 | Hybrid Cardiovascular Set | 33961 |
| 61920 | CARDIOVASCULAR UNIVERSAL SET | 33961 |
| 65000 | E.N.T. SET | 33961 |
| 65020 | E.N.T. Set | 33961 |
| 65043 | C-SECTION SET | 33961 |
| 65790 | OPHTHALMIC SET | 33961 |
| 65800 | TUR SET | 33961 |
| 66010 | UNIVERSAL SET | 33961 |
| 66100 | REINFORCED UNIVERSAL SET | 33961 |
| 66200 | UNIVERSAL SET STANDARD | 33961 |
| 66300 | UNIVERSAL SET STANDARD | 33961 |
| 669600 | ACUTE THORACIC SET | 33961 |
| 692300 | PLASTIC SURGERY SET | 33961 |
| 694000 | DENTAL SET | 33961 |
| 694110 | C-SECTION SET | 33961 |
| 694135 | C-SECTION SET | 33961 |
| 694140 | C-SECTION SET | 33961 |
| 694145 | C-SECTION SET | 33961 |
| 694240 | LAPAROSCOPY SET ABDO-PERINEAL | 33961 |
| 694241 | LAPAROSCOPY SET ABDO-PERINEAL | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 694242 | LAPAROSCOPY SET ABDO-PERINEAL | 33961 |
| 694245 | LAPAROSCOPY SET | 33961 |
| 694265 | LAPAROSCOPY SET | 33961 |
| 694500 | PFANNENSTIEL SET | 33961 |
| 694640 | CARDIOVASCULAR SET | 33961 |
| 694700 | CARDIOVASCULAR SET | 33961 |
| 695000 | DELIVERY SET | 33961 |
| 695400 | OPHTHALMIC SET | 33961 |
| 696110 | GYNAECOLOGY AND CYSTOSCOPY SET | 33961 |
| 696310 | TUR SET | 33961 |
| 696450 | LITHOTOMY SET | 33961 |
| 696500 | GYNAECOLOGY LAPAROSCOPY SET | 33961 |
| 696600 | GYNAECOLOGY LAPAROSCOPY SET | 33961 |
| 696700 | GYNAECOLOGY SET | 33961 |
| 696810 | GYNAECOLOGY SET | 33961 |
| 696940 | HEAD SET | 33961 |
| 697000 | E.N.T. SET | 33961 |
| 697100 | LAPAROTOMY SET | 33961 |
| 697250 | NECK SET | 33961 |
| 697260 | THYROID SET | 33961 |
| 697600 | APERTURE SET BASIC | 33961 |
| 697640 | E.N.T. SET | 33961 |
| 698220 | ANGIOGRAPHY SET | 33961 |
| 698260 | ANGIOGRAPHY RADIALIS SET | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 698740 | UNIVERSAL SET BASIC | 33961 |
| 698780 | UNIVERSAL SET STANDARD | 33961 |
| 698900 | UNIVERSAL SET BASIC | 33961 |
| 699010 | PAEDIATRIC SET BASIC | 33961 |
| 699054 | UNIVERSAL SET STANDARD | 33961 |
| 699110 | UNIVERSAL SET | 33961 |
| 699140 | UNIVERSAL SET STANDARD | 33961 |
| 699145 | UNIVERSAL SET BASIC | 33961 |
| 699175 | REINFORCED UNIVERSAL SET | 33961 |
| 699180 | REINFORCED UNIVERSAL SET | 33961 |
| 699340 | UNIVERSAL SET STANDARD | 33961 |
| 699354 | UNIVERSAL SET STANDARD | 33961 |
| 699540 | UNIVERSAL SET STANDARD | 33961 |
| 699600 | UNIVERSAL SET STANDARD | 33961 |
| 699640 | UNIVERSAL SET STANDARD | 33961 |
| 699700 | UNIVERSAL SET STANDARD | 33961 |
| 790000 | UNIVERSAL SET | 33961 |
| 790500 | UNIVERSAL SET | 33961 |
| 793000 | UNIVERSAL SET | 33961 |
| 793500 | SET BASIC | 33961 |
| 794000 | UNIVERSAL SET | 33961 |
| 795500 | SPLIT SHEET SET | 33961 |
| 796000 | SPLIT SHEET SET | 33961 |
| 798000 | EXTREMITY SET | 33961 |
| 798500 | EXTREMITY SET | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 80005471 | SPINAL SET | 33961 |
| 80011660 | HEAD TURBAN SET | 33961 |
| 80574671 | HEAD TURBAN SET | 33961 |
| 80974401 | CYSTOSCOPY SET | 33961 |
| 84511411 | ABDOMINAL LAPAROSCOPY SET | 33961 |
| 84511451 | OPHTHALMIC SET | 33961 |
| 84511461 | OPHTHALMIC SET | 33961 |
| 888112 | GYNAECOLOGY SET | 33961 |
| 888113 | GYNAECOLOGY SET | 33961 |
| 888142 | CRANIOTOMY SET | 33961 |
| 888212 | GYNAECOLOGY SET | 33961 |
| 888222 | TUR SET | 33961 |
| 888224 | TUR SET | 33961 |
| 888225 | TUR SET | 33961 |
| 888226 | TUR SET | 33961 |
| 888228 | TUR SET | 33961 |
| 888242 | CRANIOTOMY SET | 33961 |
| 902496 | GYNAECOLOGY AND CYSTOSCOPY SET | 33961 |
| 903014 | VERTICAL ISOLATION SET | 33961 |
| 903016 | VERTICAL ISOLATION SET | 33961 |
| 903020 | GYNAECOLOGY AND LAPAROSCOPY SET | 33961 |
| 903026 | VERTICAL ISOLATION SET | 33961 |
| 903163 | OPHTHALMIC SET | 33961 |
| 903165 | OPHTHALMIC SET | 33961 |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---|---|---|
| 903167 | OPHTHALMIC SET | 33961 |
| 903286 | OPHTHALMIC SET | 33961 |
| 903328 | C-SECTION SET | 33961 |
| 903355 | C-SECTION SET | 33961 |
| 903440 | C-SECTION SET | 33961 |
| 904194 | UNIVERSAL SET BASIC | 33961 |
| 904383 | DELIVERY SET | 33961 |
| 904730 | ANGIOGRAPHY SET | 33961 |
| 905020 | URO AND GYNAECOLOGY SET | 33961 |
| 914341 | DELIVERY SET | 33961 |
| 915322 | OPHTHALMIC SET | 33961 |
| 925982 | GYNAECOLOGY SET | 33961 |
| 925984 | GYNAECOLOGY SET | 33961 |

**Title: Mölnlycke Procedure Trays MDD Article 12 (former Class IIa trays)**



We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

| | |
|---|---|
| Sterilisation after assembly: | *EtO, Ethylene Oxide* |
| CE certificate | *CE 01966* |
| Certificate issued by | *BSi (0086)* |

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

**Signed for and on behalf of Mölnlycke Health Care**

*Authorised Signatory:*

*Name of signing person*
RA Manager, Medical Devices

| Product reference | Product Name | Product Description / included devices | GMDN code |
|---|---|---|---|
| **See products linked to this document in the ERP system.** | | | |

*Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.*

**Signed for and on behalf of Mölnlycke Health Care**

*Authorised Signatory:*

*Name of signing person*

RA Manager, Medical Devices

Wir

We

**B. Braun Melsungen AG**
**Carl-Braun-Straße 1**
**34212 Melsungen**
**Deutschland/Germany**

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

**Procedure Kits**

(Artikelnummern siehe Anlage )

**Procedure Kits**

(article numbers see attachment )

a) die gegenseitige Kompatibilität der Geräte in Übereinstimmung mit den Anweisungen des Herstellers geprüft wird, und dass alle Operationen in Übereinstimmung mit diesen Anweisungen ausgeführt werden, und das

a) mutual compatibility of the devices in accordance with the manufacturers instructions is proven and that all operations are carried out in accordance with these instructions, and that

b) das System oder die Behandlungseinheit verpackt und sachdienliche Informationen für die Nutzer, einschließlich der einschlägigen Informationen von den Herstellern mitgeliefert werden; und

b) the system or procedure pack is packed and supplied with relevant information to users incorporating relevant information from the manufacturers; and

c) die gesamte Tätigkeit in geeigneter Weise intern überwacht und kontrolliert wird.

c) the whole activity is subjected to appropriate methods of internal control and inspection.

d) (Falls das System / Behandlungseinheit sterilisiert wird).
Die Sterilisation ist gemäß den Anweisungen des Herstellers erfolgt.

d) (If the system / procedure pack has been sterilised).
The sterilisation has been carried out in accordance with the manufacturer's instructions.

Diese Erklärung basiert auf der Grundlage

declaration is made on basis of

- Artikel 12 Absatz 2 der Medizinprodukte Richtlinie 93/42/EWG
- Paragraph 10 des Medizinproduktegesetzes (Medizinproduktegesetz, 7. August 2002)

- Article 12 part 2 of Medical Device Directive 93/42/EEC
- Paragraph 10 of Medical Devices Act (Medizinproduktegesetz, 7. August 2002)

Dieses Zertifikat ist gültig für die im Anhang I genannten Procedure Kits hergestellt von der B. Braun Melsungen AG, 34209 Melsungen, Deutschland

This certificate is valid for the procedure kits mentioned in the Attachment I manufactured by B. Braun Melsungen AG, 34209 Melsungen, Germany

**Datum der ersten Erklärung**
2015-01

**Date of first declaration**
2015-01

**Gültig bis**
2024-05-26

**Valid until**
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
**Head of Quality Management CoE VS**

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
**Head of Regulatory Affairs**

| Art.-Nr. / Art. No. | Artikelbezeichnung | Article description | Enthält Komponenten der Klasse/ contains components of Class |
|---|---|---|---|
| 5010687 | Hahnbankset Uni Münster | Hahnbankset Uni Münster | IIa |
| 5010690 | Feinnadelset KH-Stuttgart | Feinnadelset KH-Stuttgart | IIa |
| 5010691 | Angiodyn Coroset Villingen-Schwenningen | Angiodyn Coroset Villingen-Schwenningen | IIa |
| 5010701 | Coroset Nagold | Coroset Nagold | IIa |
| 5010709 | PTCA Set | PTCA Set | IIa |
| 5010714 | Port-Punktionsset | Port-Punktionsset | IIa |
| 5010720 | EP-Set | EP-Set | IIa |
| 5010727 | Laser-Set, KSSP Aarau | Laser-Set, KSSP Aarau | IIa |
| 5010744 | Toimenpidesetti Seinäjoe ks, röntgen | Toimenpidesetti Seinäjoe ks, röntgen | IIa |
| 5010764 | Angiodynset 3FRR35 15360 | Angiodynset 3FRR35 15360 | IIa |
| 5010778 | Angio-Neuro-Set Heinrich-Braun-Krankenhaus | Angio-Neuro-Set Heinrich-Braun-Krankenhaus | IIa |
| 5010782 | Pädiatrie-Set Uni Homburg | Pädiatrie-Set Uni Homburg | IIa |
| 5010783 | Set steril pentru Angiografie | Set steril pentru Angiografie | IIa |
| 5010786 | Hybrid Set Hirslanden Zürich | Hybrid Set Hirslanden Zürich | IIa |
| 5010794 | Angiosetti PHKS, ELFYS | Angiosetti PHKS, ELFYS | IIa |
| 5010800 | Bowl 90ml, Round, Blue | Bowl 90ml, Round, Blue | I |
| 5010801 | Tab. Neuro / Angiograpfia – H. Egas Moniz | Tab. Neuro / Angiograpfia – H. Egas Moniz | IIa |
| 5010804 | Epiduraalsetti Vaasan ks | Epiduraalsetti Vaasan ks | IIa |
| 5010805 | EPU Set HZ Dresden | EPU Set HZ Dresden | IIa |
| 5010806 | Hahnbankset Nagold | Hahnbankset Nagold | IIb |
| 5010808 | Contrast-Saver HKZ Rotenburg | Contrast-Saver HKZ Rotenburg | IIa |
| 5010811 | NNI – Angiography Set | NNI – Angiography Set | IIa |
| 5010817 | UNI-Set_Novomed | UNI-Set_Novomed | IIa |
| 5010820 | Angiodyn-Schale, 60 ml, transp. | Angiodyn-Bowl, 60 ml, transp. | Is |
| 5010830 | Cover Drape 90 X 90 CM | Cover Drape 90 X 90 CM | I |
| 5010833 | Sahlgrenska Sotra | Sahlgrenska Sotra | IIa |
| 5010840 | Kidney Dish Blue | Kidney Dish Blue | I |
| 5010850 | Cover Drape 152 X 228 CM | Cover Drape 152 X 228 CM | I |
| 5010860 | Angiodyn-Schale, 120 ml, transp. | Angiodyn-Bowl, 120 ml, transp. | Is |
| 5010868 | PTCA Set Bad Rothenfelde | PTCA Set Bad Rothenfelde | IIa |
| 5010871 | Angiodyn HKL-Set Bad Tölz | Angiodyn HKL-Set Bad Tölz | IIa |
| 5010874 | Untersuchungskittel, Gr. XL | Untersuchungskittel, Gr. XL | Is |
| 5010878 | Skejby højre side pakke | Skejby højre side pakke | IIa |
| 5010880 | Paineemittaussetti malli 2 | Paineemittaussetti malli 2 | IIb |

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 012974 0608 Rev. 00**

**Manufacturer:** **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

**Product Category(ies):** **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713168177

**Valid from:** 2020-05-06
**Valid until:** 2024-05-26

**Date,** 2020-05-14

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

# EC Certificate

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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 012974 0608 Rev. 00**

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TÜV SÜD
Product Service

# Certificate

## No. Q5 012974 0606 Rev. 00

**Holder of Certificate:** **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

**Certification Mark:**

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

**Scope of Certificate:** **Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA guide wires and sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial punture cannula, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713160067

**Valid from:** 2019-10-08
**Valid until:** 2022-09-30

**Date,** 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

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A4 / 07.17


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# Certificate

## No. Q5 012974 0606 Rev. 00

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

./.


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B BRAUN

# Konformitätserklärung
# Declaration of Conformity

| | |
|---|---|
| Document-No.: | 39.05.641 |
| Revision-No.: | 15 |
| Effective Date: | 2020-05-19 |
| Page: | 1 of 2 |

Wir | We

**B. Braun Melsungen AG**
**Carl-Braun-Straße 1**
**34212 Melsungen**
**Deutschland/Germany**

erklären in eigener Verantwortung,
dass das/die Produkt/e

**Arteriofix**

Arterienpunktionskanülen, Arterien-Katheter-Set
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 7

**Benannte Stelle**
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

**Ausgestellte Bescheinigung(en):**
G1 012974 0608 Rev. 00

**Datum der ersten CE-Kennzeichnung**
1996-06-13

**Gültig bis**
2024-05-26

hereby declare in our own responsibility
that the product/s

**Arteriofix**

Arterial puncture needle, Arterial Catheter Set
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above

**Classification**
according to annex IX of the
Council Directive named above
Class IIa / Rule 7

**Notified Body**
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

**Certificate(s) issued:**
G1 012974 0608 Rev. 00

**Date of first CE-marking**
1996-06-13

**Valid until**
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
**Head of Quality Management CoE VS**

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
**Head of Regulatory Affairs**

## Anlage I / Attachment I

| Art.-Nr. / Art. No. | Artikelbezeichnung | Article description | Klasse / Class |
|---|---|---|---|
| 5206316 | Arteriofix Art.-Kath.-Set 22G/80 mm | Arteriofix 22G/80 mm | IIa |
| 5206324 | Arteriofix Art.-Kath.-Set 20G/80 mm | Arteriofix 20G/80 mm | IIa |
| 5206332 | Arteriofix Art.-Kath.-Set 20G/160 mm | Arteriofix 20G/160 mm | IIa |
| 5206359 | Arteriofix Art.-Kath.-Set 18G/160 mm | Arteriofix 18G/160 mm | IIa |
| 5206345 | Arteriofix Art.-Kath.-Set 18G/80 mm | Arteriofix 18G/80 mm | IIa |

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Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 010066 0426 Rev. 00**

**Manufacturer:** **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

**Product Category(ies):** **Implants, Instruments and Devices (for detailed information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713159626

**Valid from:** 2019-07-27

**Valid until:** 2024-05-26

**Date,** 2019-07-16

Stefan Preiß
Head of Certification/Notified Body


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TÜV SÜD Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 010066 0426 Rev. 00**

**Facility(ies):**

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants


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Product Service

# Certificate

## No. Q5 010066 0435 Rev. 00

**Holder of Certificate:** **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

**Certification Mark:**

**Scope of Certificate:** **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713175266

**Valid from:** 2020-06-01
**Valid until:** 2023-05-31

**Date,** 2020-05-27

Christoph Dicks
Head of Certification/Notified Body


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Product Service

# Certificate

## No. Q5 010066 0435 Rev. 00

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESCULAP AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

- Surgical and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories
- Collagen implants


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Management Service

# CERTIFICATE

**The Certification Body**
**of TÜV SÜD Management Service GmbH**

certifies that

## Aesculap AG

**Am Aesculap-Platz, 78532 Tuttlingen, Germany**
**Carl-Braun-Straße 1, 34212 Melsungen, Germany**

has established and applies
a Quality Management System for

**Design and Development, Technical Service, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material and Tissue Adhesive**

**Aesculap AG Tuttlingen**

- Surgical and dental instruments
- Joint Implants (hip, knee)
- Spinal Implants
- Implants for Osteosynthesis
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Veterinary instrumentation
- Other surgical accessories
- Instrument Management System
- Collagen implants

**Aesculap AG Melsungen**

- Implants for replacement of connective tissue
- Tissue adhesive
- Local haemostatic

An audit was performed, Order No. **70062209**.

Proof has been furnished that the requirements according to

## ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-06-01** until **2023-05-31**.

Certificate Registration No.: **12 100 21724 TMS**.

Product Compliance Management
Munich, 2020-05-20

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

MÖLNLYCKE
HEALTH CARE

Göteborg 2006-08-07

To Whom It may concern:

We hereby declare that,

Following Mölnlycke Health Care surgical drapes comply with the High Performance requirements of EN13795:

- Klinidrape® laminated Patient Drapes
- BARRIER® reinforced and laminated Patient Drapes
- Klinidrape® and BARRIER® Stockinettes and plastic/laminated Leggings
- Klinidrape® and BARRIER® Table Covers and Mayo Stand Covers

Following Mölnlycke Health Care surgical drapes comply with the Standard Performance requirements of EN13795:

- Klinidrape® Utility Drapes
- BARRIER® non-reinforced Patient Drapes (less critical area)
- Klinidrape® and BARRIER® nonwoven OP-tapes (less critical area)
- Klinidrape® and BARRIER® fluid repellent Leggings and Supplementary Products (less critical area)

Mölnlycke Health Care standard Klinidrape® and BARRIER® Surgical Gowns comply with the Standard Performance requirements of EN13795.

Mölnlycke Health Care reinforced Klinidrape® and BARRIER® Surgical Gowns comply with the High Performance requirements of EN13795

Mölnlycke Health Care Clean Air Suits comply with the performance requirements of EN13795

Anders Odmyr
International Technical Support Manager
Drapes and Sets

Mölnlycke Health Care AB
Box 130 80, SE 402 52 Göteborg, Sweden
Visitor: Gamlestadsvägen 3C
www.molnlycke.com
Tel: +46 31 722 30 00
Fax: +46 31 722 34 00
Reg. No 556547-5489
Seat Göteborgs Kommun